# Adverse Event Reporting, CTMS, and CDUS Survey Results

| | | N | % | N | % |
|---|---|---|---|---|---|
| **Total Number of Responding Institutions** | | **16** | | | |
| **Number of Centers with Legacy System(s)** | | **13** | **81%** | | |
| **Total Number of Legacy Systems** | | | | **15** | |
| **Type of AE Data Collection (N=15)** | | | | | |
| AE Grade | | | | 14 | **93%** |
| AE Expectedness | | | | 7 | **47%** |
| AE Attribution | | | | 13 | **87%** |
| AE relatedness to the Protocol | | | | 9 | **60%** |
| CTCAE Toxicity | | | | 9 | **60%** |
| Protocol Status | | | | 13 | **87%** |
| Study Phase | | | | 13 | **87%** |
| Risk-Benefit relationship of the research | | | | 3 | **20%** |
| Other | | | | 3 | **20%** |
| None/No response | | | | 1 | **7%** |
| **Current Systems Functionality (N=15)** | | | | | |
| Automated AE Grading | | | | 4 | **27%** |
| AE Data Collection | | | | 7 | **47%** |
| AE Reporting | | | | 5 | **33%** |
| Messaging of SAEs | | | | 1 | **7%** |
| Routing AEs | | | | 1 | **7%** |
| Integrated AE Repository | | | | 7 | **47%** |
| Vocabulary Management | | | | 3 | **20%** |
| Participant Self-Reporting | | | | 2 | **13%** |
| Public Access to AE Information | | | | 1 | **7%** |
| Other | | | | 2 | **13%** |
| None/No response | | | | 5 | **33%** |
| **Summarization of Comments** | | | | | |
| Need harmonization of AE terms | | | | | |
| **Interaction with the caBIG AE system (N=16)** | | | | | |
| Full Implementation | **A** | 4 | **25%** | | |
| Interface with Legacy AE systems | **B** | 6 | **38%** | | |
| Other | **C** | 3 | **19%** | | |
| | **A & B** | 2 | **13%** | | |
| | **B & C** | 1 | **6%** | | |
| **Summarization of Comments** | | | | | |
| Streamlined and secure reporting of AEs to External Agencies (e.g., NCI, CTEP, FDA) | | | | | |
| Interface as much as possible the legacy AE systems with caBIG AE system | | | | | |
| Interaction with the caBIG AE system is dependent on the product that is developed | | | | | |
| **Legacy AE Reporting systems/databases (N=16)** | | | | | |
| **One (1) Legacy System** | | **11** | **69%** | | |
| Vendor System | | 6 | | | |
| Homegrown System | | 4 | | | |
| No response | | 1 | | | |
| **More than One (1) Legacy System** | | **2** | **13%** | | |
| Vendor System | | 1 | | | |
| Homegrown System | | 3 | | | |
| **No Legacy AE System** | | **3** | **19%** | | |
| | | | | | |

## Adverse Event Reporting, CTMS, and CDUS Survey Results

| | | | | | |
|---|---|---|---|---|---|
| **Total Number of Responding Institutions** | | **16** | | | |
| **Number of Centers with Legacy System(s)** | | **13** | **81%** | | |
| **Total Number of Legacy Systems** | | | | **15** | |
| **Operating System (N=15)** | | | | | |
| Web-based | | | | 1 | **7%** |
| Windows | | | | 7 | **47%** |
| No response | | | | 4 | **27%** |
| **Database (N=15)** | | | | | |
| Oracle | | | | 7 | **47%** |
| Advanced Revelation | | | | 1 | **7%** |
| MS Access | | | | 2 | **13%** |
| SQL | | | | 3 | **20%** |
| No response | | | | 4 | **27%** |
| | | | | | |
| **Program Language (N=15)** | | | | | |
| ASP.net | **A** | | | 1 | **7%** |
| Cold Fusion | **B** | | | 1 | **7%** |
| FoxPro 8 | **C** | | | 0 | **0%** |
| Java | **D** | | | 4 | **27%** |
| MS Access | **E** | | | 1 | **7%** |
| Oracle Forms and Reports | **E** | | | 1 | **7%** |
| Rbasic | **G** | | | 1 | **7%** |
| Visual Basic | **I** | | | 0 | **0%** |
| | **B & C** | | | 1 | **7%** |
| | **D & I** | | | 1 | **7%** |
| No response | | | | 4 | **27%** |
| **Type of CTMS and CDUS Data Capture and Reporting Capabilities (N=16)** | | | | | |
| **CTMS** | | | | | |
| Data entry into ACES locally and then electronic data transfer to the CTMS database | **A** | 6 | **38%** | | |
| Application to Application data transfer (Legacy Clinical Trials system to CTMS database) | **B** | 0 | **0%** | | |
| Other - Paper, fax | **C** | 1 | | | |
| | **A & B** | 1 | **6%** | | |
| | **A, B, & C** | 1 | **6%** | | |
| Not Reporting/Not Required | | 5 | **31%** | | |
| No Response | | 2 | **13%** | | |
| **CDUS** | | | | | |
| Data entry into CDUS via web-based data entry application | **A** | 7 | **44%** | | |
| Data entry into CDUS via CTEP-FTP site | **B** | 0 | **0%** | | |
| Application to Application data transfer (Legacy Clinical Trials system to CDUS via the CTEP-FTP site) | **C** | 1 | **6%** | | |
| Application to Application data transfer (Legacy clinical trials system to CDUS) | **D** | 0 | **0%** | | |
| Create a file from the legacy clinical trials system and send to CDUS via FTP | **E** | 0 | **0%** | | |
| | **A & B** | 2 | **13%** | | |
| | **A, C, & D** | 1 | **6%** | | |
| | **D & E** | 1 | **6%** | | |

## Adverse Event Reporting, CTMS, and CDUS Survey Results

| | | | | | |
|---|---|---|---|---|---|
| **Total Number of Responding Institutions** | | **16** | | | |
| **Number of Centers with Legacy System(s)** | | **13** | **81%** | | |
| **Total Number of Legacy Systems** | | | | **15** | |
| Other - Paper, fax | | 1 | **6%** | | |
| Not Reporting/Not Required | | 1 | **6%** | | |
| No Response | | 2 | **13%** | | |

| **Summarization of Comments** |
|---|
| Use of multiple methods to transfer the AE reports |
| Tedious, labor intensive process with some double data entry. |
| Want a secure automated data transfer |
| **Issues/Barriers with CTMS and/or CDUS report systems - Summarization of Comments (Refer to the comments section for all the comments)** |
| Unsecure electronic data transfer |
| Several iterations of data validation after submission and resubmissions before submission is accepted |
| Unclear CDUS expectations of reporting the data |
| Nonstandard coding of data and abbreviations |
| Naming of entities is inconsistent - I.e., same drugs will be abbreviated differently in different studies and |
| Fixed file lengths of submission fields - many of the file lengths are too short |
| Theradex - Vague data export specifications and vague or no table specifications |
| CTMS system automatically defaults to the description rather than the CTC/CTCAE term - this generates potentially unnecessary clarification of data already entered |
| Clarifications of data are not always sent in a timely manner. Extra time is then spent on clarifying previous submitted data making it difficult to stay current with present data submissions. |